

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**METACEL PHARMACEUTICALS,
LLC,**

Plaintiff,

v.

**RUBICON RESEARCH PRIVATE
LIMITED,**

Defendant.

Civil Action No. 2:21–CV-19463-EP-JRA

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**PLAINTIFF’S OPPOSITION TO DEFENDANT’S MOTION FOR
LEAVE TO FILE COUNTERCLAIM SUBJECT TO THE CONDITION
THAT THE COUNTERCLAIM BE BIFURCATED AND STAYED**

Arnold B. Calmann
Katherine A. Escanlar
SAIBER LLC
One Gateway Center, 9th Floor
Newark, NJ 07102-5308
T: (973) 622-3333
abc@saiber.com
kescanlar@saiber.com

Erin N. Winn
**ARNALL GOLDEN GREGORY
LLP**
171 17th Street, NW
Suite 2100
Atlanta, Georgia 30363
erin.winn@AGG.com

Kevin M. Bell
Scott A.M. Chambers, Ph.D.
Matthew D. Zapadka
Richard J. Oparil
**ARNALL GOLDEN GREGORY
LLP**
2100 Pennsylvania Avenue, NW
Suite 350S
Washington, D.C. 20037
(202) 677-4930
kevin.bell@AGG.com
scott.chambers@AGG.com
matthew.zapadka@AGG.com
richard.oparil@AGG.com

Attorneys for Plaintiff Metacel Pharmaceuticals, LLC

Table of Contents

| | |
|--|----|
| INTRODUCTION | 1 |
| ARGUMENT | 5 |
| I. Rule 13(e) does not allow for the relief Rubicon seeks because Rubicon has improperly delayed filing its counterclaim. | 5 |
| A. Rule 13(e) does not allow the relief Rubicon seeks at this time because the alleged injury occurred when Metacel filed its Complaint on October 29, 2021. | 6 |
| B. Rule 13(e) does not apply because Rubicon actually seeks an entirely new bifurcated cause of action, rather than a supplemental pleading in this lawsuit. | 7 |
| II. Rule 15 does not allow for the relief sought by Rubicon because Rubicon’s counterclaim is untimely and prejudicial, and Rubicon’s counterclaim for sham litigation is futile. | 8 |
| A. Rubicon’s proposed counterclaim is untimely and highly prejudicial to Metacel. | 9 |
| B. Rubicon’s Counterclaim is Brought in Bad Faith and for a Dilatory Motive. | 12 |
| C. Rubicon’s Counterclaim is Futile because it cannot show that Metacel’s case is objectively baseless or that Metacel possessed anticompetitive intent. | 13 |
| III. Rubicon’s motion for leave should be denied and there is no justification to bifurcate and stay its counterclaim. | 18 |
| Conclusion | 18 |

TABLE OF AUTHORITIES

| | Page(s) |
|---|----------------|
| Cases | |
| <i>Duke Univ., Allergain, Inc. V. Akorn, Inc.</i> , No. 3:18-cv-14035-BRMTJB, 2019 WL 4410284 (D.N.J. Sept. 16, 2019)..... | 18 |
| <i>Organon Inc. v. Mylan Pharms., Inc.</i> , 293 F. Supp. 2d 453 (D. N.J. 2003) | 16, 17 |
| <i>Perrigo Co. v. AbbVie Inc.</i> , No. 21-3026, 2022 WL 2870152 (3d Cir. July 21, 2022)..... | 8, 9, 11, 13 |
| <i>Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.</i> , 508 U.S. 49 (1993)..... | 15 |
| Statutes | |
| 21 U.S.C. § 355(c)(3)(C) | 6 |
| Other Authorities | |
| Federal Rules of Civil Procedure Rule 13(e) | <i>passim</i> |
| Rule 15 | 5 |
| Rule 15’s | 1 |
| Rule 16..... | 8 |
| Rule 42(b)..... | 4 |

INTRODUCTION

On May 12, 2023, Rubicon Research Private Limited (“Rubicon”) filed its Motion for Leave to File Counterclaim Subject to the Condition That the Counterclaim be Bifurcated and Stayed (ECF NO. 130) including its brief in support (“Motion,” ECF No. 130-4). Rubicon’s Motion asks this Court to grant it leave to amend its Answer under Fed. R. Civ. P. 13(e), but this is procedurally infirm as discussed further below. Rubicon seeks to include a counterclaim for sham litigation against Plaintiff Metacel Pharmaceuticals, LLC (“Metacel”), which is based on the notion that Metacel’s Complaint is “objectively baseless” for alleging that Rubicon’s product identified in Abbreviated New Drug Application 214445 (“the ANDA product”) infringes U.S. Patent No. 10,610,502 (“the ’502 Patent”).

The Court should deny Rubicon’s Motion because it lacks diligence, is unduly delayed, and highly prejudicial to Metacel. While Rubicon’s Motion seeks leave under Rule 13(e), that rule does not allow for the relief that Rubicon seeks. This is because Rubicon attempts to circumvent the restrictions of Rule 13(e) and skirt Rubicon’s failure to timely raise its compulsory counterclaim for sham litigation, by asking to stay and bifurcate its counterclaim until after resolution of the underlying infringement claim.

If the Court were to stay and bifurcate Rubicon's counterclaim as Rubicon asks, this would have the practical effect of casting a compulsory counterclaim for sham litigation as an entirely new case because it would be initiated only after resolution of the infringement claim, including its own scheduling order and complex issues to resolve, regardless of whether they could have been properly resolved in this litigation. Rubicon does not identify any procedural avenue that would make its sought-after outcome proper, but granting Rubicon's relief would be highly prejudicial to Metacel. This prejudice arises at least because it allows Rubicon to hold a counterclaim in abeyance as a threat against Metacel until the resolution of the infringement claim without having to actually pursue its antitrust claim. The outcome Rubicon seeks prejudices Metacel, has no basis in the rules or the Court's precedent, and would only lead to increased cost and inefficiency at the Court. Indeed, the Court identified all these concerns during the Parties' March 21, 2023 conference with the Court, but Rubicon's motion ignores the Court's caution and proceeds with this Motion anyway. (ECF 101 at 19:14-23, 21:16-22).¹

¹ During the March 21, 2023 status conference held among the Parties and the Court, Rubicon proposed bifurcating the sham litigation counterclaim from the underlying infringement suit. (ECF 101). To that, the Court identified several reasons why it would likely be apprehensive to grant such relief based on the burden on the Court, the lack of efficiency, and costs to the Court, saying:

THE COURT: Okay. I mean I'm -- I will tell you I
 15 don't -- I don't know that the District Court will be
 16 amenable to bifurcate these issues; right? Because, they're

Not only is Rubicon's Motion procedurally improper, but Rule 15's prejudice-balancing overwhelmingly favors Metacel. Rubicon waited nearly 19 months to seek leave to file its counterclaim for sham litigation in a Hatch-Waxman case, when it knew or should have known as of the time of filing of Metacel's Complaint that it intended to file that counterclaim. This constitutes undue delay and highly prejudices Metacel at least partly due to the fact that the deadlines for fact discovery, expert disclosures, and the time to amend pleadings have all expired under the Scheduling Order. Additionally, if the Court were to stay and bifurcate the antitrust counterclaim, that cause of action is held in the background as a threat against Metacel while Rubicon is not required to take any affirmative action to litigate that

17 inter-related, and so why have two trials when you can have
 18 one? Resources are limited and it is important to use the
 19 resources respectably and -- and efficiently. And, to
 20 bifurcate it, while it is appropriate in some cases, I think
 21 would create issues in this one. So, I'm not ready to make
 22 any decision on whether to bifurcate or not, but let me hear
 23 from Mr. Bell on this issue.

(ECF 101 at 19:14-23)

THE COURT: Okay. So, I will give you -- another
 17 twenty day extension on this. And, the -- the reason for it,
 18 for purposes of the record, is because it sounds like you're
 19 trying to resolve this case. And, I -- I don't want to be a
 20 stumbling block if there's progress to be made. But, I will
 21 say that because of resource my expectation is that will not
 22 be bifurcated, that it would be litigated all in one case.

Id. at 21:16-22.

claim until the conclusion of the infringement claim. Indeed, tactical advantages would flow to Rubicon simply by virtue of Rubicon's failure to timely raise its counterclaim.

Even if Rubicon could meet the standard for the timely filing of a motion, Rubicon's counterclaim for sham litigation is also futile. To succeed on a sham litigation claim, a claimant must prove that the "sham" litigation was objectively baseless and that the litigant sought to use the litigation as an anticompetitive device.

Here, when considering the futility of the sham litigation claim, the Court does not need to go any further than considering whether Metacel's case is objectively baseless. At this stage, perhaps the best place for the Court to consider whether Metacel had a reasonable belief that it could succeed on its infringement claim is in the summary judgment briefing pending before this Court. Metacel's detailed summary judgment briefing, supported by expert testimony, and other factual evidence demonstrates that Metacel's infringement action was not objectively baseless. (ECF 102-08). In fact, those filings show that Rubicon infringes the '502 Patent.

Further, if the Court did go so far as to consider Metacel's intent for filing the infringement claim against Rubicon, it should be apparent based on the facts of the case that Metacel filed its infringement claim simply to prohibit a patent infringer—Rubicon—from infringing the '502 Patent. Rubicon does not identify any facts other

than the institution of the infringement case itself that evidence Metacel acted with any anticompetitive intent. In fact, if Rubicon's position were correct, this would mean that all patentees would be acting with anticompetitive intent when asserting a patent against an infringing generic looking to enter the market. That outcome is not one proscribed by the patent laws or the Hatch-Waxman Act. For at least those reasons, Rubicon cannot establish that Metacel possessed the requisite subjective intent for anticompetitive harm.

For at least the foregoing reasons, and those forth below, the Court should deny Rubicon's motion.

ARGUMENT

I. Rule 13(e) does not allow for the relief Rubicon seeks because Rubicon has improperly delayed filing its counterclaim.

The Court should deny Rubicon's motion to amend for at least two reasons. First, Third Circuit precedent explains why Rule 13(e) should not allow for a sham litigation counterclaim asserted after the filing of the initial answer when the party asserting that counterclaim knew to assert that counterclaim as of the time of the alleged anticompetitive injury, *i.e.*, the filing of the original complaint. Second, Rubicon is attempting to improperly shoehorn a new bifurcated cause of action into a supplemental pleading under Rule 13(e), which is improper under the rule.

A. Rule 13(e) does not allow the relief Rubicon seeks at this time because the alleged injury occurred when Metacel filed its Complaint on October 29, 2021.

The issue here is straightforward. Rubicon attempts to rely on Rule 13(e) because Rubicon contends that its counterclaim did not mature until it received tentative approval for its ANDA product. (Motion at 5). Particularly, Rubicon posits that the “specific antitrust injury incurred by Rubicon began from March 13, 2023,” which coincides with the date on which Rubicon purportedly obtained Tentative Approval from the FDA for its ANDA product. *Id.* at 6.

However, Rule 13(e) does not provide the procedural vehicle to assert Rubicon’s counterclaim because Rubicon is incorrect about its characterization of the time of accrual of its counterclaim. The Third Circuit has held that “[i]n the sham litigation context, the injury generally occurs when the lawsuit, which is alleged to have been a sham, is filed.” *Perrigo Co. v. AbbVie Inc.*, No. 21-3026, 2022 WL 2870152, at *4 (3d Cir. July 21, 2022). Metacel filed this lawsuit on October 29, 2021, which is within the statutorily proscribed 45 days from the date it received Rubicon’s Paragraph IV notice—and nearly 19 months ago. (ECF No. 1). Accordingly, to the extent that Rubicon was improperly excluded from the market covered by the ’502 Patent, that exclusion was triggered on the date that Metacel filed its Complaint, thereby starting the clock for the time in which Rubicon was to

timely assert its compulsory counterclaim for sham litigation. *See Perrigo*, 2022 WL 2870152, at *4-*6.

Rubicon's Answer, filed on January 21, 2022, did not include any counterclaims. (ECF No. 7). Rubicon has not previously sought leave to amend its Answer or assert counterclaims. Rubicon has not taken any other affirmative action before May 12, 2023 (the date of the filing of this Motion) to assert its counterclaim. And Rubicon has not presented any excuse or justification for this delay, such as the discovery of any new evidence. Accordingly, Rubicon should not be allowed to assert its counterclaim after waiting this late in the litigation to assert it.

B. Rule 13(e) does not apply because Rubicon actually seeks an entirely new bifurcated cause of action, rather than a supplemental pleading in this lawsuit.

Rubicon also asks the Court to bifurcate its proposed counterclaim from the underlying infringement claims and to stay its counterclaim until the conclusion of Metacel's claims against Rubicon. (Motion at 2). Rule 13(e) does not proscribe any procedure for the bifurcation and staying of a counterclaim. Rubicon does not explain how Rule 13(e) could allow for the relief it seeks and Rubicon does not cite any legal authority to justify its request for conditional stay and bifurcation. Accordingly, Rubicon has failed to meet the standard and the Motion should be stricken.

To the extent the Court wishes to consider Rubicon's application to stay and bifurcate, this would likely be considered under Fed. R. Civ. P. 42(b), a rule not even cited in Rubicon's motion. Rule 42(b) dictates when separate trials are appropriate, *i.e.*, for "convenience, to avoid prejudice, or to expedite and economize." Applying Rule 42(b) further highlights the untenability of Rubicon's position because bifurcating and staying Rubicon's untimely and baseless counterclaim is neither convenient to the parties nor the Court, and substantially prejudices Metacel, all while slowing the pace of overall resolution, impacting the likelihood the Parties reach settlement, and dramatically increasing the expense of the overall litigation. Indeed, Your Honor already explained reasons militating against bifurcation during the parties' status conference on March 21, 2023. *Supra*, n.1. Rather than following the Court's guidance, Rubicon chose to file its motion to amend expressly conditioned on bifurcation and a stay.

For at least these reasons, the Court should deny Rubicon's motion under Rule 13(e).

II. Rule 15 does not allow for the relief sought by Rubicon because Rubicon's counterclaim is untimely and prejudicial, and Rubicon's counterclaim for sham litigation is futile.

The Court should deny Rubicon's motion seeking to add a sham litigation counterclaim, which Rubicon also seeks to have bifurcated and stayed. (Motion at 2). There is no basis for Rubicon's sham litigation claim. The claim, and procedural

posture thereof, is highly prejudicial to Metacel because it aims an antitrust lawsuit at Metacel, to be initiated at some date uncertain, which sits a threat to Metacel and for which Metacel can seek no reprieve (other than settlement) until after the resolution of the underlying infringement claim. Denial of Rubicon's motion is warranted under Rule 15.

A. Rubicon's proposed counterclaim is untimely and highly prejudicial to Metacel.

As discussed above, Third Circuit practice mandates that, to be timely, a litigant must assert a sham litigation counterclaim in a Hatch-Waxman suit when initially answering the complaint. *Perrigo*, 2022 WL 2870152, at *4-*6. Instead of adhering to this Circuit's clear precedent, the Court's Scheduling Order, and the applicable rules, Rubicon chose to delay nearly 19 months before it sought leave to assert a counterclaim against Metacel. Rubicon attempts to obscure the glaring length of time between the filing of Metacel's Complaint and the assertion of its counterclaim by asking this Court to bifurcate and stay its counterclaim. Rubicon's request ignores Your Honor's guidance to the contrary (ECF 101 at 19:14-23, 21:16-22) and should be denied for at least four reasons.

First, the automatic 30-month stay mandated by 21 U.S.C. § 355(c)(3)(C) began in October 2021 ends in March 2024. It is highly unlikely, if not impossible, that the current schedule trial schedule tethered to this date could be maintained while also including an antitrust sham litigation claim. Litigating a complex antitrust

claim would require reopening fact discovery, expanding expert discovery, and the possibility for dispositive motion practice. Rubicon's request to bifurcate and stay is a litigation strategy lacking any legal support and Rubicon cites to none.

Rubicon's request is simply an attempt to salvage the filing of an unduly delayed counterclaim, while improperly casting that claim as a new suit altogether. Notably, if Rubicon were able to file its counterclaim as a separate suit—it cannot because it is a compulsory counterclaim—then there would be no need for amending its Answer and asserting its claim as part of its case. Instead, Rubicon has chosen an overtly prejudicial route, essentially hold a claim in abeyance to create a litigation risk to Metacel without ever actually needing to take action to litigate its case until some uncertain point in the future. Indeed, granting Rubicon's motion would subject Metacel to the accusation of violating federal antitrust law for an unknown period of time, leading to damage to Metacel's business in the interim. Further, Metacel would not be able to obtain fact discovery, expert evidence, or file a summary judgment motion on the allegations in this case, because those deadlines have already passed.

Second, the proposed bifurcation and stay of the counterclaim is unrelated to whether Rubicon unduly delayed the assertion of that claim. Indeed, the request to bifurcate and stay does not change the fact that Rubicon waited nearly 19 months after Metacel filed its Complaint to file its counterclaim when it should have asserted that counterclaim when answering the Complaint, the timing of which is dictated by

the purported exclusion from the market that occurred at the time of the filing of the Complaint. *Perrigo*, 2022 WL 2870152, at *4-*6. While Rubicon contends that the date of the Tentative Approval of its ANDA Product is the triggering event, that assertion is at odds with the rules and case law. *See id* (“In the sham litigation context, the injury generally occurs when the lawsuit, which is alleged to have been a sham, is filed.”) Consequently, Rubicon’s proposal to stay and bifurcate does nothing to remedy its delay or the prejudice associated with it.

Third, Rubicon knew or should have known that it intended to file a counterclaim for sham litigation when Metacel filed its Complaint, or at least as early as when Rubicon filed its initial Answer. In fact, Rubicon alleges that it timely filed its Answer to Metacel’s Complaint on January 21, 2022, and then “[f]rom that point forward, Metacel’s suit was objectively baseless in that no reasonable litigant could realistically expect success on the merits.” (ECF No. 130-2 at Defendant Rubicon’s Counterclaim ¶¶ 24-25 (Exhibit A to the Declaration of Timothy H. Kratz)). ***Thus, the clock to measure Rubicon’s delay has been running since at least January 21, 2022, because, as alleged by Rubicon itself, it was fully aware of its belief*** (though misplaced) that Metacel’s infringement claim was sham litigation.

Fourth, Rubicon’s delay has been overtly tactical and prejudicial. Rubicon raised the specter of a sham litigation claim to this Court when it filed its letter to Your Honor on October 11, 2022. (ECF No. 57). There, Rubicon told the Court that

it was considering filing a sham litigation counterclaim at some time uncertain. But rather than seek leave to file its counterclaim, Rubicon requested that the Court modify the schedule in this case to enlarge the time in which pleadings could be amended. *See id.* On October 19, 2022, Metacel opposed Rubicon's proposed modification to the Scheduling Order as violative of Rule 16, frivolous, and inequitable due to Rubicon's obstructive actions during discovery. (ECF No. 63). The Court did not modify the Scheduling Order following receipt of that letter and Rubicon did not file any further related correspondence or motions until the present Motion, which was filed eight months after the time to amend pleadings under the Scheduling Order. (ECF No. 25 ¶ 33). In the meantime, Rubicon did not take any discovery on the issue and waited until months after the close of fact discovery and after filing its summary judgment motion to seek amendment of its pleading to add a counterclaim. There is simply no justification for Rubicon's delay and the Court should dismiss the Motion because of this undue delay and the resulting prejudice.

B. Rubicon's Counterclaim is Brought in Bad Faith and for a Dilatory Motive.

It is hard to conceive of Rubicon's actions being anything other than bad faith or for a dilatory motive. Rubicon lied-in-wait for nearly 19 months before seeking leave to file its counterclaim, while possessing the awareness that it intended to file a sham litigation claim during this entire time. Rubicon's Motion does not address Your Honor's concerns, which were raised with the parties during the March 21,

2023 status conference with the Court. *Supra*, n.1. Rubicon's counterclaim is not likely resolved within the 30-month stay period governed by statute. And Rubicon has no excuse for its delay given that it knew that it intended to file its sham litigation at least as early as January 21, 2022. Consideration of all these factors demonstrate that Rubicon's counterclaim is now being asserted for the purpose of influencing settlement, complicate proceedings before this Court and add associated expense, and implicate Metacel for a potential antitrust violation to be litigated at some point uncertain. Rubicon's counterclaim is purely sought in bad faith and as a dilatory motive.

C. Rubicon's Counterclaim is Futile because it cannot show that Metacel's case is objectively baseless or that Metacel possessed anticompetitive intent.

Notwithstanding the procedural infirmities of Rubicon's Motion and the reasons that it should be denied on those failures alone, Rubicon's counterclaim fails to allege a cognizable sham litigation claim.

Rubicon's counterclaim for sham litigation is futile and highly unlikely to succeed. For a litigation to be a "sham," the basis for the litigation must be objectively baseless and the litigant must have had the subjective motivation for an anticompetitive effect. *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-60 (1993). Rubicon cannot establish the fundamental issue of objective baselessness, and so the Court need not even consider Metacel's subjective

intent. *Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 461 (D.N.J. 2003) (“Only if the litigation is found to be objectively baseless may a court proceed to examine the litigant's subjective motivation.”). However, should the Court wish to consider subjective intent, Rubicon’s allegations are lacking.

Throughout this litigation, Rubicon has made it known that it wished to seek summary judgment as soon as possible because, in its view, Rubicon does not infringe the ’502 Patent. After several attempts and multiple procedural missteps including premature and improper attachment of a motion to a letter seeking leave to file (ECF No. 53) and the failure to include a statement of facts with its motion (ECF No. 99), Rubicon was finally able to file a motion for summary judgment in condition for the Court’s consideration—on March 21, 2023 (nearly 18 months after institution of this litigation). (ECF No. 98). If Rubicon believed that its sham litigation counterclaim had any merit or factual support at any point during this 18-month window, certainly it would have sought leave to file its counterclaim without waiting until nearly two-thirds of the way through the 30-month stay of the Hatch-Waxman litigation had waned.

Notwithstanding the impropriety of Rubicon’s delay in asserting its counterclaim, Rubicon’s sham litigation claim is futile because Metacel’s infringement claim was not objectively baseless. The summary judgment briefing pending in this Court is perhaps the most comprehensive representation of the merits

of Metacel's infringement claim, and not only does Metacel have an objectively reasonable (and likely successful) basis to assert its patent infringement claim, but Rubicon's contrary legal positions are meritless. As discussed throughout Metacel's opposition to Rubicon's summary judgment brief, Rubicon's summary judgment motion rests solely on attorney argument that is either unsupported or factually incorrect. *See, e.g.*, ECF Nos. 102, 108. The relative merits of those motions speak for themselves, but they show that there is no basis to conclude that Metacel's infringement case could be considered objectively baseless, particularly when weighing Metacel's legally and scientifically supported opposition to Rubicon's summary judgment motion (ECF 103-08) to Rubicon's motion based solely on attorney argument (ECF 88-90, 102).

Thus, lacking the objective baselessness that is required to establish an antitrust claim under the Sherman Act, the Court need not consider the issue of intent. *Organon*, 293 F. Supp. 2d at 461. However, if the Court needs to reach the issue of intent, Rubicon is unlikely to succeed on that basis as well. Metacel's intent was evidenced by its desire to enforce its patent covering its approved Ozobax® product, not to advance any anticompetitive effect. The '502 Patent issued on April 7, 2020. Thus, the Ozobax® market covered by the '502 Patent existed for little over a year before Rubicon attempted to enter the market with a generic product that infringed that patent. Not only is this a fledgling market, but Rubicon is the first to

enter the specific market covered by the '502 Patent. (ECF No. 130-2 at Defendant Rubicon's Counterclaim ¶ 21 (Exhibit A to the Declaration of Timothy H. Kratz)).

Metacel has done nothing more here than assert its rightfully granted patent, which a patentee is free to do to ensure the value of its patent rights. Rubicon has taken no other action to produce an anticompetitive effect. If Rubicon were correct, then every patent holder that asserts a patent against a generic drug maker would be subject to an antitrust claim, and resulting delay for the generic to enter the market is insufficient to demonstrate that anticompetitive intent. *Duke Univ., Allergan, Inc. v. Akorn, Inc.*, No. 3:18-CV-14035-BRMTJB, 2019 WL 4410284, at *6 (D.N.J. Sept. 16, 2019) ("The Supreme Court has dispelled the notion that an antitrust plaintiff could prove a sham merely by showing that its competitor's purposes were to delay [the plaintiff's] entry into the market and even to deny it a meaningful access to the appropriate ... administrative and legislative fora." (internal quotations omitted)). Indeed, Metacel's decision to enforce a patent in a single lawsuit, without allegations of any other anticompetitive harm, is insufficient to establish a claim for sham litigation.

Not only is Rubicon's counterclaim futile for failing to satisfy the threshold requirements to allege the elements of a sham litigation, but Rubicon's counterclaim is also futile when considering Rubicon's definition of the relevant market for baclofen and the relative market power of the two parties in this suit.

Regarding the market for baclofen, Rubicon’s counterclaim takes an overly simplistic, and likely incorrect view, of the definition of the market related to Metacel’s Ozobax® product or the baclofen market generally. Rubicon’s counterclaim defines the relevant market as “the market for baclofen oral solution for its approved indication(s).” (ECF No. 130-2 at Defendant Rubicon’s Counterclaim ¶ 46 (Exhibit A to the Declaration of Timothy H. Kratz)). As admitted by Rubicon, there are other baclofen products on the market. *Id.* ¶ 47. In fact, according to the FDA’s Orange Book, there are 86 approved baclofen drugs, many of which are oral formulations, and six of those approvals are owned by Rubicon. (Zapadka Declaration ¶¶ 4-6, Exhibit A).

Regarding the relative market power of the two parties in the suit, Rubicon is a large multinational company with many drug approvals that has distributed over a billion products and is an entity with the capability of exerting significantly more market power than Metacel, a small company in Athens, Georgia. (Zapadka Declaration ¶¶ 7-8, Exhibit B; ECF No. 1 ¶ 3). If anything, given Rubicon’s dilatory conduct and the logical inference that they are the party with the greater market power due to their size, product listing, and international reach, Rubicon is the more likely party with the intent to engage in anticompetitive behavior by attempting to harm Metacel with a dilatory counterclaim. When considering all of the relative market aspects of the two parties and facts of this case, Rubicon’s allegations that

Metacel had the intent to engage in anticompetitive behavior are highly untenable and unlikely to be successful.

Accordingly, Rubicon's sham litigation counterclaim is futile, thereby warranting dismissal of its motion for leave.

III. Rubicon's motion for leave should be denied and there is no justification to bifurcate and stay its counterclaim.

For at least the reasons discussed above, Rubicon's motion for leave and the request for bifurcation and stay should be denied because Rubicon does not have a legal basis for the stay and bifurcation. Furthermore, Rubicon requested bifurcation and stay of its counterclaim, even after Your Honor expressed concern that route would complicate satisfaction of the statutory 30-month stay window, delays resolution of the overall dispute, and increases expense and complexity of the matter. Therefore, the Court should deny Rubicon's motion for leave to file its counterclaim along with its motion to bifurcate and stay the counterclaim for sham litigation.

Conclusion

For the foregoing reasons, the Court should deny Rubicon's Motion.

Dated: May 22, 2023

Respectfully Submitted,

SAIBER LLC

Attorneys for Plaintiff

Metacel Pharmaceuticals, LLC.

Kevin M. Bell

Scott A.M. Chambers, Ph.D.

Matthew D. Zapadka

Richard J. Oparil

**ARNALL GOLDEN GREGORY
LLP**

1775 Pennsylvania Ave NW

Suite 1000

Washington, D.C. 20006

Tel: (202) 677-4930

kevin.bell@AGG.com

scott.chambers@AGG.com

matthew.zapadka@AGG.com

richard.oparil@AGG.com

/s/ Arnold B. Calmann

Arnold B. Calmann

Katherine A. Escanlar

One Gateway Center, 9th Floor

Newark, NJ 07102-5308

Tel: (973) 622-3333

abc@saiber.com

kescanlar@saiber.com

Erin N. Winn

**ARNALL GOLDEN GREGORY
LLP**

171 17th Street NW

Suite 2100

Atlanta, GA 30363

Tel: (404) 873-8721

Erin.winn@agg.com